

6,346,112). Applicants respectfully submit that this rejection is improper.

Claim 1 provides:

An annuloplasty method comprising the steps of:

providing clips each having two end points which are separated from each other when the clip is in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration; and

placing said clips around an annulus by causing both of the two end points of each of said clips in said open configuration to penetrate tissue of said annulus at two circumferentially separated positions, whereby said clips reduce diameter of said annulus.

Referring to FIGS. 1A and 1B, the Examiner advanced that Adams discloses an annuloplasty method involving providing clips each having two end points, which are separated from each other when the clip is in an open configuration. The Examiner further advanced that the Adams clips are placed around an annulus to penetrate tissue of the annulus at two circumferentially separated positions, whereby the clips reduce the diameter of the annulus.

The Adams invention is directed to hemostatic clips for compressing tissue and causing the hemostasis of bleeding blood vessels, particularly gastrointestinal bleeders (col. 2, lines 50-54). In addition to causing the hemostasis of individual blood vessels, the Adams invention contemplates the use of hemostatic clips to cause the hemostasis of bleeding ulcer beds by reducing blood flow thereto (col.5, lines 8-21).

Contrary to the Examiner's assertion, Adams' FIG. 1B does not show a clip having two end points which are separated from each other when the clip is in an open configuration. FIG. 1B shows a clip with blunt ends when in an open configuration.

Adams also does not disclose using clips to reduce the diameter of an annulus. First, it is not clear what annulus the Examiner is contemplating. Further, nothing in Adams suggests that clip 10 is even capable of reducing the diameter of an annulus. For example, nothing in Adams suggests that the length of the clip's rear member 13 shortens to change the diameter of something such as an annulus.

The procedure depicted in FIG. 6 also does not support the Examiner's assertion. The rear members of clips 62 appear to correspond to the rear members 13 of clips 10 and share the same inability to change in length. Adams is simply devoid of any suggestion to perform an annuloplasty with clips that reduce the diameter of an annulus.

Claim 5 provides:

A clip delivery device for annuloplasty, said device comprising:

a plurality of clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration;

a clip-holder supporting said clips in said open configuration; and

a pusher for pushing a specified number of said clips at a time by causing said two end points thereof to leave said device simultaneously together.

In view of the Examiner's reference to element 93 as corresponding to Applicants' claimed pusher, it appears that the Examiner is basing the rejection of claim 5 on the embodiment of FIG. 9. However, the circular clip depicted in FIG. 9 does not have two end points. Such end points also appear unnecessary in view of the pointed end 91 of hypodermic needle 90, which holds the clip 80 in its second configuration, while it is delivered to a target location along the gastrointestinal tract (col.6, lines 1-7). In further contrast to Applicants' claim 5, Adams also does not describe a clip-holder supporting a plurality of clips in connection with the embodiment of FIG. 9. Hypodermic needle 90 only carries a single clip and the pusher bar only acts on that single clip.

Claims 9-18 were rejected under 35 U.S.C. §102(a) as being anticipated by Kuehn, et al. (US 6,165,183). This rejection also is improper.

Claim 9 provides:

A mitral valve repair method comprising the steps of:

providing clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed

configuration by reducing distance between said end points when in said open configuration;

placing an annuloplasty ring about an annulus; and

attaching said ring around said annulus by causing said clips to pass through said ring.

Kuehn, et al. disclose mitral or tricuspid valve repair involving fastening/securing opposing heart valve leaflets. Kuehn, et al. do not disclose or suggest placing an annuloplasty ring about an annulus or attaching such a ring around an annulus, let alone using clips having two end points to pass through the annuloplasty ring.

Claim 15 provides:

A mitral valve replacement method comprising the steps of:

providing clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration;

removing mitral valve portions to be replaced;

placing a prosthesis sewing cuff therefor where said valve portions have been removed;

attaching said prosthesis sewing cuff to a tissue around said removed valve portions by causing said clips to penetrate both said prosthesis sewing cuff and said tissue.

The Keuhn, et al. patent is devoid of any disclosure involving removing mitral valve portions or placing a prosthesis sewing cuff therefor where the valve portions have been removed.

Although further discussion of the dependent claims is not presently necessary, Applicants submit that the dependent claims also contain allowable subject matter. For example, the cited references also do not disclose the flexible member or tissue piercing member of claim 2, the claimed clips loaded in a delivery device as described in claim 3, the pair of springs for pushing the clips of claim 7, or any of the subject matter of claims 10-14 or 16-18.

If the Examiner maintains any of the foregoing rejections, Applicants request that the Examiner clearly point to specific examples in the cited references that support any rejection so maintained. If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the number provided below.

CONCLUSION

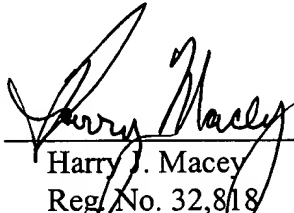
The undersigned believes that all claims now pending in this application are in condition for allowance and respectfully requests the issuance of a formal Notice of Allowance at an early date.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due, including additional claims fees, in connection with the filing of this document to Deposit Account No. 50-1947 referencing Attorney Docket No. CSI-2012.

Respectfully submitted,

Date: January 13, 2003

By: _____


Harry J. Macey
Reg. No. 32,818
Attorney for Applicant

Law Office of Harry J. Macey
1301 Shoreway Road, Suite 121
Belmont, California 94002-4106
Telephone: 650.654.9555
Facsimile: 650.654.9554